Exhibit 1

Nichols Institute Diagnostics

March 25, 2005

IMPORTANT – PRODUCT WITHDRAWAL
NICHOLS INSTITUTE DIAGNOSTICS
BIO-INTACT PTH (1-84) ASSAY (Catalog No. 62-7040)
LOT 62-402598

Attention: Laboratory Director

Recent internal testing indicates that Lot 62-402598 of the Nichols Advantage Bio-Intact (1-84) PTH Assay does not meet the following performance specifications stated in the Directional Insert ("DI"): (1) functional sensitivity; (2) reproducibility; (3) parallelism; and (4) interferences.

Nichols Institute Diagnostics ("NID") recommends that customers stop using Lot 62-402598 immediately. Remaining materials should be discarded. Please return the attached form to (1) verify your receipt of the notice, (2) document the amount of product destroyed, and (3) receive credit for the product destroyed.

NID is taking this action based on the results of its internal testing. This action is not the result of customer complaints or reported patient problems.

NID recommends that laboratories act in accordance with their Standard Operating Procedures. The information below is intended to assist laboratories in this evaluation:

A. The DI indicates that PTH tests should be used in conjunction with serum calcium levels and other clinical data to assist the clinician in making patient management decisions.

B. Our testing indicates that laboratories may wish to re-evaluate prior results from Lot 62-402598 that were below 15 pg/mL.

C. **Performance Characteristics of Lot 62-402598**

1. **Functional Sensitivity**: Our testing demonstrates that the **functional sensitivity is below 5.0 pg/mL**. This differs from information in the DI, which states that the estimated Limit of Quantitation (functional sensitivity) is less than 4.0 pg/mL.

2. **Reproducibility**: Our testing demonstrates a **higher %CV** for within-run imprecision and total imprecision than stated in the DI. For samples between 4-1800 pg/mL, the within-run imprecision range is 2.2-20.7% CV, and the total imprecision range is 2.3-25.1% CV. This differs from information in the DI, which provides a recovery range for 4 samples of 2.2-5.5% CV for within-run imprecision and 5.1-10.9% CV for total imprecision.

3. **Parallelism**: Our testing demonstrates a **higher observed dilution % recovery** than the data reported in the DI. For samples with values between 5-1800 pg/mL, the test data show that the mean % recovery is 109%, and the maximum value for any dilution sample is 140%. For samples with values between 50-1800 pg/mL, the test data show that the mean % recovery is 105%, and the maximum value for any dilution sample is 114%. This differs from the information in the DI, which provides a maximum % recovery for any dilution sample of 110%.

4. **Interferences**: Our testing demonstrates performance changes with respect to the hemoglobin and protein interference information stated in the Limitations section of the DI:

(a) **Hemolyzed Samples May Show Over-recovery.** The DI states that grossly hemolyzed samples should not be tested. Our testing demonstrates that samples showing any visible signs of hemolysis should not be tested.

(b) **Interference With Exogenously Added Protein.** Our testing demonstrates that exogenous protein spiked into patient samples over **2000 mg/dL may interfere with the assay**, defined as recovery within ±10% of the control values. This differs from the information in the DI, which states that protein up to 6000 mg/dL (in addition to the endogenous concentration of protein in the sample) does not interfere with the assay defined as recovery within ±10% of the control values.

Please call NID Technical Services at (800) 286-4643, ext. 5222 if you have any questions about this product withdrawal.

NID apologizes for the inconvenience associated with this product withdrawal. The Food and Drug Administration is aware of this action.

Nichols Institute Diagnostics

1311 Calle Batido
San Clemente, California 92673
949.940.7200
800.286.4NID

Nichols Institute Diagnostics

Product Withdrawal Return Response Form

Nichols Advantage® Bio-Intact (1-84) PTH
Catalog #: 62-7040
Lot Number: 62-402598

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the March 25, 2005 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I have destroyed withdrawn product.

Any adverse events associated with withdrawn product? ☐ Yes ☐ No
If yes, please explain: _____

_____

_____

Name: _____

Title: _____

Tel. Number: _____

Firm Name: _____

Address: _____

City/State: _____

(PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO)

Fax Number: (949) 940-7440
Attn. Robert L. Schmidt
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

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Nichols Institute Diagnostics

Product Withdrawal Return Response Form

Nichols Advantage® Bio-Intact (1-84) PTH
Catalog #: 62-7040
Lot Number: 62-402622

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the March 25, 2005 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I have destroyed withdrawn product.

Any adverse events associated with withdrawn product? ☐ Yes ☐ No
If yes, please explain: _____

_____

_____

Name: _____

Title: _____

Tel. Number: _____

Firm Name: _____

Address: _____

City/State: _____

(PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO)

Fax Number: (949) 940-7440
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Product Withdrawal Return Response Form

Nichols Advantage® Bio-Intact (1-84) PTH
Catalog #: 62-7040
Lot Number: 62-402622

Please check ALL appropriate boxes.

☐ I have read and understand the withdrawal instructions provided in the March 25, 2005 letter.

☐ I have checked my stock and have quarantined inventory consisting of _____ units.

☐ I have destroyed withdrawn product.

☐ I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**)

Any adverse events associated with withdrawn product? ☐ Yes ☐ No
If yes, please explain: _____

_____

Name: _____

Title: _____

Tel. Number: _____

Firm Name: _____

Address: _____

City/State: _____

(PLEASE FAX OR MAIL COMPLETED RESPONSE FORM TO)

Fax Number: (949) 940-7440
Attn. Robert L. Schmidt
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673

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Nichols Institute
Diagnostics

April 22, 2005

IMPORTANT – PRODUCT WITHDRAWAL

NICHOLS INSTITUTE DIAGNOSTICS
Nichols Advantage ACTH® Cartridge
(Catalog No. 62-7004) lot 62- 500040

Attention: Laboratory Director

Nichols Institute Diagnostics (NID) is informing you that internal testing reflects that the Nichols Advantage ACTH Cartridge lot # 62-500040 does not meet claims in the Directional Insert ("DI") concerning correlation with the IRMA ACTH Assay Catalog # 40-2194.

The Directional Insert states a linear regression formula of $y = 1.02 x + 0.04$ with a population of 115 samples, with IRMA ACTH values ranging from 1.0 to 462 pg/mL. The results of internal testing of lot 62-500040 are $y = 0.72x + 0.04$, $r = 0.99$ with a population of 35 samples, with IRMA ACTH values ranging from 1.0 to 1464 pg/mL.

Nichols Institute Diagnostics ("NID") recommends that customers stop using this Cartridge Lot immediately. Remaining materials should be discarded. Please return the attached form to (1) verify your receipt of the notice, (2) document the amount of product destroyed, and (3) receive credit for the product destroyed.

NID is taking this action based on the results of its internal testing and as a result of customer complaints that the product is not consistent with the method correlation reported in the DI. NID has received no customer complaints of reported patient problems.

NID recommends that laboratories evaluate this information, consult with their medical director, and act in accordance with their Standard Operating Procedures. The DI indicates that ACTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Please call NID Technical Services at (800) 286-4643, ext. 5222 if you have any questions about this product withdrawal. For outside the U.S please contact the appropriate field office (NID Germany at +49(0) 6101.8022.0 or NID France at +33 (0) 1 53.24.99.44) or authorized distributor.

NID apologizes for the inconvenience associated with this product withdrawal.

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Nichols Institute
Diagnostics

April 29, 2005

IMPORTANT – PRODUCT WITHDRAWAL

NICHOLS INSTITUTE DIAGNOSTICS
Nichols Advantage ACTH® Cartridge(Catalog No. 62-7004)
Amendment to April 22 notification:
Withdrawal of lot 62-404296

Attention: Laboratory Director

Nichols Institute Diagnostics (NID) informed you on April 22nd that Nichols Advantage ACTH Cartridge lot # 62-500040 did not meet claims in the Directional Insert ("DI") concerning correlation with the IRMA ACTH Assay Catalog # 40-2194. NID reported that the Directional Insert states a linear regression formula of $y = 1.02 x + 0.04$ with a population of 115 samples, with IRMA ACTH values ranging from 1.0 to 462 pg/mL. The results of internal testing of lot 62-500040 are $y = 0.72x + 0.04$, $r = 0.99$ with a population of 35 samples, with IRMA ACTH values ranging from 1.0 to 1464 pg/mL.

Based on internal testing, lot 62-404296 is expected to perform in a similar manner. NID is therefore withdrawing lot 62-404296.

Nichols Institute Diagnostics ("NID") recommends that customers stop using Cartridge Lot 62-404296 immediately. Remaining materials should be discarded. Please return the attached form to (1) verify your receipt of the notice, (2) document the amount of product destroyed, and (3) receive credit for the product destroyed.

NID is taking this action based on the results of its internal testing and as a result of customer complaints that the product is not consistent with the method correlation reported in the DI. NID has received no customer complaints of reported patient problems.

NID recommends that laboratories evaluate this information, consult with their medical director, and act in accordance with their Standard Operating Procedures. The DI indicates that ACTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Please call NID Technical Services at (800) 286-4643, ext. 5222 if you have any questions about this product withdrawal. For outside the U.S please contact the appropriate field office (NID Germany at +49(0) 6101.8022.0 or NID France at +33 (0) 1 53.24.99.44) or authorized distributor.

NID apologizes for the inconvenience associated with this product withdrawal.

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Nichols Advantage®

IMPORTANT -- PRODUCT NOTIFICATION

Customer Bulletin No. CB-05-17-AD

Date: **April 29, 2005**

Attention: **Laboratory Management**
Nichols Advantage® Operators

Subject: **IMPORTANT PRODUCT NOTIFICATION - Nichols Advantage ACTH Cartridges (Catalog No. 62-7004) lots # 62-304299, 62-304303, 62-400896, 62-403355, 62-403197, and 62-404199.**

Nichols Institute Diagnostics (NID) is informing you that internal testing reflects that the Nichols Advantage ACTH expired Cartridge lots # 62-304299, 62-304303, 62-400896, 62-403355, 62-403197, and 62-404199 may not have met claims in the Directional Insert ("DI") concerning correlation with the IRMA ACTH assay catalog # 40-2194.

The Directional Insert states a linear regression formula of $y = 1.02 x + 0.04$ calculated using 115 samples, with IRMA ACTH values ranging from 1.0 to 462 pg/mL. The results of internal testing indicates as follows:

Lot # of NA ACTH Cartridge	Linear regression formula	Sample Size	Range of IRMA ACTH Values
62-304299	y = 0.80x + 7.8	29	7-206 pg/mL
62-400896	y = 0.89x + 1.6	50	1-161 pg/mL
62-404199	y = 0.73x + 0.9	137	1-383 pg/mL

NID does not have method correlation data for lots 62-304303, 62-403355, and 62-403197. All of the lots covered by this bulletin are expired and should not be in use. NID is providing this information to assist laboratories in evaluating test results.

NID is taking this action based on the results of its internal testing and as a result of customer complaints that the product is not providing results consistent with the method correlation reported in the DI. NID has received no customer complaints of reported patient problems.

NID recommends that laboratories evaluate this information, consult with their medical director, and act in accordance with their Standard Operating Procedures. The DI indicates that ACTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Please contact the Technical Services Department at the numbers listed below if you have questions or need additional information. For the United States call 1-800-286-4NID. For outside the U.S. contact the appropriate field office or authorized distributor

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